DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on July 15, 2009 has been entered.

Applicant's amendment filed on July 15, 2009 is acknowledged and has been entered. Claims 110 and 117 have been amended. Claims 1-109, 111-116 and 118-120 have been canceled. Claims 110 and 117 are pending.

Claims 110 and 117 are discussed in this Office action.

Previous Grounds of Rejection

The previous rejections of claims 105, 107, 118 and 119 as being anticipated by Patel is withdrawn in view of the cancellation of those claims.

Response to Amendment

The declaration under 37 CFR 1.132 filed July 15, 2009 is sufficient to overcome the rejection of claims 110 and 117 based upon 35 U.S.C. 102(a) as being anticipated by Nagarkatti.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Jay Cinamon on September 23, 2009.

The application has been amended as follows:

110. An isolated allelic variant consisting of R1 and R3 loci, wherein said R1 locus consists of GT dinucleotide repeats from nucleotide position 125 from the 5' end of SEQ ID NO:1 and said R3 locus consists of GT dinucleotide repeats from nucleotide position 87 from the 5' end of SEQ ID NO:2 of Signal Transducer and Activator of Transcription - 6 (STAT-6) gene for use in predicting susceptibility of a human subject to atopic asthma,

wherein the isolated variants have haplotype 17_15, where the haplotype has 17 repeats on the R1 locus and 15 repeats on R3 locus, and

wherein the isolated variants have haplotype 16_15, where the haplotype has 16 repeats on the R1 locus and 15 repeats on the R3 locus, and

wherein these haplotypes are associated with susceptibility to asthma.

117. An isolated allelic variant consisting of R1 and R3 loci, wherein said R1 locus consists of GT dinucleotide repeats from nucleotide position 125 from the 5' end of SEQ ID NO:1 and said

R3 locus consists of GT dinucleotide repeats from nucleotide position 87 from the 5' end of SEQ ID NO:2 of Signal Transducer and Activator of Transcription - 6 (STAT-6) gene for use in predicting susceptibility of a human subject to atopic asthma,

wherein the isolated variants have haplotype 17_14, where the haplotype has 17 repeats on the R1 locus and 14 repeats on R3 locus, and

wherein the isolated variants have haplotype 23_16, where the haplotype has 16 repeats on the R1 locus and 23 repeats on the R3 locus, and

wherein the isolated variants have haplotype 24_16, where the haplotype has 24 repeats on the R1 locus and 16 repeats on the R3 locus, and

wherein these haplotypes are associated with protection from asthma.

Allowable Subject Matter

Claims 110 and 117 are allowed.

The following is an examiner's statement of reasons for allowance:

While the prior art has characterized a GT dinucleotide repeat within exon 1 of the STAT-6 gene, which corresponds to the R3 locus in claims 110 and 117 (see Figure 1), other than the work of Nagarkatti, the art has not recognized or characterized the GT dinucleotide repeat which corresponds to the R1 locus in claims 110 and 117. Furthermore, while the closest prior art, Patel, teaches isolation of STAT-6 sequences which comprise GT dinucleotide repeats including the R1 and R3 loci, Patel does not teach isolated variants or a full length sequence which includes the specified number of repeats at both loci in the haplotypes, as claimed. Patel teaches a sequence which has 22 repeats at R1 and 15 repeats at R3. The number of repeats taught by Patel does not anticipate or render obvious either claim 110 or 117. Claim 110

requires an isolated variant with either 16 or 17 repeats at R1 and 15 repeats at R3. While Patel teaches a sequence which includes 15 repeats at R3, the sequence does not have 16 or 17 repeats at the R1 locus, as claimed. Regarding claim 117, the sequence of Patel also does not teach the number of repeats at either the R1 or the R3 locus as claimed. Therefore, the claims are novel and non-obvious over the teachings of Patel.

Finally, a careful review of the prior art shows that it would not have been obvious to isolate allelic variants with haplotype sequences comprising the specified number of repeats at the R1 locus together with the R3 locus because, other than the teaching of Nagarkatti, the R1 repeat was not studied in detail. A careful search of the prior art and nucleic acid databases also showed a lack of references which disclosed or taught haplotype sequences comprising the combination of specific numbers of dinucleotide repeats together as claimed. Therefore, the claimed invention is not obvious over the prior art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to STEPHANIE K. MUMMERT whose telephone number is (571)272-8503. The examiner can normally be reached on M-F, 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Stephanie K. Mummert/
Examiner, Art Unit 1637

SKM

/GARY BENZION/
Supervisory Patent Examiner, Art Unit 1637